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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,816	08/25/2000	Michael R. Yeaman	660081.415C1	6324

41552 7590 05/22/2006

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/648,816

Applicant(s)

YEAMAN ET AL.

Examiner

Chih-Min Kam

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 67-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 67-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Status of the Claims*

1. Claims 67-79 are pending.

Applicants' amendments filed on November 28, 2005 and March 6, 2006 are acknowledged, and applicants' response has been fully considered. Claim 67 has been amended, and claims 67-79 are examined.

In the Office Action dated May 27, 2005, Examiner has indicated that upon reconsideration, claims 70-74 and 76-79 are included for examination because claims 70-74 and 76-79 are directed to amino acid sequences (SEQ ID NOs: 4-8 and 10-13), which are encompassed by claim 67, therefore the status of claims 70-74 and 76-79 are no longer withdrawn.

### **Withdrawn Claim Rejections - Obviousness Type Double Patenting**

2. The previous rejection of claims 67-69 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of co-pending application 10/225,562, is withdrawn in view of the amendment to the claims in application 10/225,562.

### **Claim Rejections-Obviousness Type Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 67-69, 76 and 79 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U. S. Patent 6,743,769. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 67-69, 76 and 79 in the instant application disclose an isolated antimicrobial peptide consisting of an amino acid sequence having 13-74 amino acids with a 7 amino acid core sequence: aa1-aa2-aa3-aa4-aa5-aa6-aa7, where amino acid residue at each position is defined, and synthetic analogs of the 7 amino acids that retain antimicrobial activity; and an antimicrobial peptide comprising SEQ ID NO:3, 10 or 13. This is obvious variation in view of claim 1 of the patent which disclose an antimicrobial peptide comprising amino acid sequence of SEQ ID NO:3, 10, 13 or 14. Both sets of claims cite an antimicrobial peptide comprising amino acid sequence of SEQ ID NO:3, 10 or 13. Thus, claims 67-69, 76 and 79 in present application and claim 1 in the patent are obvious variations of an antimicrobial peptide comprising amino acid sequence of SEQ ID NO:3, 10 or 13.

Response to Arguments

Applicants request that the rejection be held in abeyance until there is an indication of allowable subject matter at which time Applicants will file a Terminal Disclaimer if appropriate. (page 4 of the response in the amendment filed November 28, 2005). Since a terminal disclaimer is not filed, the rejection is maintained.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 67-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 67-79 are indefinite because of the use of the term “wherein said antimicrobial peptide consists of an amino acid sequence having 13-74 amino acids”. The term cited renders the claim indefinite, it is not clear whether the antimicrobial peptide consists of an amino acid sequence of 13-74 amino acids, or comprises an amino acid sequence of 13-74 amino acids, since the term cites “consist of” (a close language) and “having” (reads as “comprising”, an open language) at the same time. Claim 67 is also indefinite as to “synthetic analogs of said 7 amino acids that retain antimicrobial activity”, it is not clear what are “said 7 amino acids”, if they are not in a peptide, and what are the synthetic analogs of these 7 amino acids that are not in a peptide. Claims 68-79 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

***Response to Arguments***

Applicants indicate claim 67 has been amended to remove the term "having", thereby obviating this ground for rejection (pages 4-5 of the response in the amendment filed November 28, 2005).

Applicants' response has been considered, however the argument is not found persuasive because the claim still recites the term "having", therefore the rejection is maintained.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 67-68 are rejected under 35 U.S.C. 102(b) as anticipated by Darveau *et al.* (U. S. Patent 5,409,898, April 1995).

Darveau *et al.* disclose a cationic oligopeptide such as Ala-Leu-Tyr-Lys-Lys-Leu-Leu-Lys-Lys-Leu-Leu-Lys-Ser-Ala-Lys-Lys-Leu-Gly which has  $\alpha$  helical amphiphilic structure and antibacterial activity (column 12, lines 31-32 and 49-54), this peptide contains the sequence of Ala-Leu-Tyr-Lys-Lys-Leu-Leu which is the synthetic analog of the 7 amino acid core sequence (Ala-Leu-Tyr-Lys-Lys-Phe-Lys) that retains antimicrobial activity (claims 67-68).

**Response to Arguments**

Applicants indicate the peptides set forth in the '898 patent differ from the claimed antimicrobial peptides by having non-identical natural amino acid residues at several positions. Natural amino acids do not represent synthetic peptide mimetics of the claimed peptides. Mimetics are chemical structures derived from bioactive peptides which imitate natural molecules (pages 4-5 of the response in the amendment filed November 28, 2005).

Applicants' response has been considered, however the argument is not found persuasive because claim 67 as amended in the amendment filed March 6, 2006 does not recite the peptide mimetics, instead, it recites synthetic analogs of said 7 amino acids that retain antimicrobial activity. Therefore, the claims are anticipated by the reference.

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6. Claims 67 and 68 are rejected under 35 U.S.C. 102(b) as anticipated by Kupsch *et al.* (The EMBO Journal 12, 641-650, 1993).

Kupsch *et al.* disclose one member of variable opacity (Opa) outer membrane proteins, OPA 65 has 236 amino acids and comprises a sequence of ARYRKWK, which is the same as the core sequence of the claimed invention (Fig. 4; see sequence match; claims 67 and 68). The OPA 65 protein would be expected to have antimicrobial activity because it contains the same core sequence as the claimed invention. The limitation “wherein said antimicrobial peptide consists of an amino acid sequence having 13-74 amino acids” reads as the antimicrobial peptide comprising 13-74 amino acids.

#### Response to Arguments

Applicants indicate claim 67 has been amended to clarify that an isolated antimicrobial peptide consists of an amino acid sequence having 13 to 74 amino acids, while Opa 65 has 236 amino acids (page 6 of the response in the amendment filed November 28, 2005).

Applicants’ response has been considered, however the argument is not found persuasive because claim 67 cites “the antimicrobial peptide consists of an amino acid sequence having (reads as comprising) 13 to 74 amino acids”, which indicates the claimed peptide can have more than 13 to 74 amino acids. Therefore, the claimed peptide is anticipated by the reference.

#### **Conclusion**

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner



**CHIH-MIN KAM**  
**PATENT EXAMINER**

CMK

May 17, 2006